NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

METACEL PHARMACEUTICALS LLC, Plaintiff, v. RUBICON RESEARCH PRIVATE LIMITED, Defendant.	No. 21cv19463 (EP) (JRA) **MEMORANDUM ORDER**

PADIN, District Judge.

Plaintiff Metacel Pharmaceuticals, LLC ("Metacel") seeks to stop Defendant Rubicon Research Private Limited ("Rubicon") from selling its generic oral baclofen solution (the "Generic"), arguing that the Generic will induce infringement of Metacel's patent (U.S. Patent No. 10,610,502 (the "'502 Patent")).[1] The Court previously granted Rubicon's summary judgment motion. *See* D.E. 137 (the "Opinion"). The Court held that there was no genuine issue of material fact as to whether the Generic's Abbreviated New Drug Application ("ANDA") label would induce a downstream user's infringement of a portion of the '502 Patent requiring storage between 2 and 8 degrees Celsius (the "Fridge Limitation"), and therefore would not infringe the '502 Patent. *Id.*

[1] Metacel markets its brand name baclofen solution under the Ozobax trademark.

Metacel now moves for this Court to reconsider. D.E. 146 ("Mot."). Rubicon opposes. D.E. 148 ("Opp'n). Metacel has not replied. For the reasons below,[2] the Court will **DENY** Metacel's motion, adhere to its original Opinion, and enter final judgment.[3]

I. LEGAL STANDARD

The "purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence." *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985), cert. denied, 476 U.S. 1171 (1986). "Reconsideration motions, however, may not be used to relitigate old matters, nor to raise arguments or present evidence that could have been raised prior to the entry of judgment." *NL Indus. v. Commercial Union Ins. Co.*, 935 F. Supp. 513, 516

To prevail on a motion for reconsideration, the movant must show: "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court ... [rendered the judgment in question]; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *U.S. ex rel. Shumann v. Astrazeneca Pharm. L.P.*,769 F.3d 837, 848-49 (3d Cir. 2014) (citing *Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999)). The standard is high and relief is to be granted sparingly. *United States v. Jones*, 158 F.R.D. 309, 314 (D.N.J. 1994). "The Court will grant a motion for reconsideration only where its prior decision has overlooked a factual or legal issue that may alter the disposition of the matter. The word 'overlooked' is the operative term in the Rule." *Andreyko v. Sunrise Sr. Living, Inc.*, 993 F. Supp. 2d 475, 478 (D.N.J. 2014) (cleaned up). Mere disagreement with the

[2] The Court decides this motion on the papers. Fed. R. Civ. P. 78; L.Civ.R. 78.1(b).
[3] Judge Almonte granted Rubicon's motion for leave to file a counterclaim. The Court respectfully defers the status of that counterclaim, currently stayed pending resolution of this motion to reconsider, to Judge Almonte for a conference. D.E. 152.

Court's decision is not a basis for reconsideration. *United States v. Compaction Sys. Corp.*, 88 F. Supp. 2d 339, 345 (D.N.J. 1999).

II. ANALYSIS

Metacel's arguments can be grouped into two categories. First, Metacel argues that it was prejudiced by the Court's consideration of Rubicon's Fridge Limitation arguments on summary judgment because the arguments were not adequately noticed or briefed. Mot. at 2-9. And if the argument had been timely raised, Metacel argues, the Court would have had the benefit of additional relevant evidence. And second, Metacel argues that the Court overlooked or misinterpreted evidence that demonstrated an issue of material fact regarding the Fridge Limitation. Mot. at 9-15.

A. Metacel was on notice of Rubicon's Fridge Limitation argument

"Local Patent Rules exist to further the goal of full and timely discovery and provide all parties with *adequate notice* with which to litigate their cases." *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-3387, 2021 U.S. Dist. LEXIS 159262, at *12 (D.N.J. Mar. 29, 2021) (cleaned up) (emphasis added).

Metacel argues that Rubicon never included its Fridge Limitation arguments in its non-infringement contentions as required by Local Patent Rules 3.6(g) and 3.2A. Metacel, Rubicon argues, waited until its summary judgment motion to identify its Fridge Limitation theory, which turned out to be dispositive. Importantly, because this a motion for reconsideration, Metacel cannot raise arguments here that it did not raise in opposition to the underlying motion. But even if the Court did consider the argument, Metacel cannot reasonably argue that it was not placed on notice of Rubicon's intent to present its Fridge Limitation theory on summary judgment.

Notice was adequate here. As Metacel recognizes, "Rubicon contended that it did not induce infringement because it did not instruct direct infringers [redacted] Mot. at 6. Indeed, Rubicon's April 20, 2022 non-infringement positions explicitly stated that its ANDA did not directly infringe the Fridge Limitation's language:

and the oral solution is stored after the determination, but prior to the administration, at from about 2 to about 8° C.	No direct infringement. No indirect infringement due to split actor.

As Metacel further recognizes, Rubicon also moved, on July 27, 2022, for leave to file a summary judgment motion including that theory. D.E. 40 at 3. Thus, to the extent that Metacel did not already know that Rubicon intended to assert that its ANDA did not directly infringe the Fridge Limitation, Metacel knew by July 27, 2022, less than a year after this case began and about six months before Metacel filed the summary judgment motion that this Court ultimately granted, that Rubicon would assert the theory.

Metacel's substantive responses are unpersuasive. First, Metacel argues that the Court did not permit Rubicon's earlier summary judgment motion, and therefore that the Fridge Limitation theory contained therein cannot have put Metacel on notice. *See* D.E. 53. And second, Metacel argues that it was Rubicon's responsibility, if it intended to argue its Fridge Limitation theory on summary judgment, to amend its non-infringement contentions accordingly.

These arguments are unpersuasive because, as discussed above, the non-infringement contentions *did* place Metacel on notice of the Fridge Limitation theory by arguing that Rubicon did not directly infringe the Fridge Limitation's language. This differentiates it from cases in which courts have found more complex non-infringement arguments untimely, including this Court's own determination in *Janssen Pharms., Inc. v. Mylan Lab'ys Ltd.*, No. 20-CV-13103, 2023 WL 3605733 (D.N.J. May 23, 2023). There, this Court found that the ANDA manufacturer did

not allege a multi-step theory of divided infringement—or even allege divided infringement at all—until its rebuttal expert report. *Id.* at *11; *see also Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, 2014 U.S. Dist. LEXIS 37002, at *17 (D.N.J. Jan. 6, 2014) (denying leave to include fifteen new prior art references not asserted earlier).

Metacel also argues that it was prejudiced because Rubicon's Fridge Limitation argument was limited to a single paragraph of its opening summary judgment brief, and not truly detailed until Metacel's reply. Mot. at 5 (citing D.E. 89 at 29). Metacel is correct that Rubicon's initial argument was short, but brevity does not equal prejudice. In that paragraph, Rubicon got right to it:

> Second, [redacted] See RUB00083 and RUB00087 at Exhibit 4. In Metacel's Infringement Contentions, Metacel references RUB00087 for the proposition that [redacted] That is the only reference Metacel makes in alleged satisfaction of this claim element. But RUB00087 does not [redacted] This is legally insufficient to satisfy the legal requirements for indirect infringement. *See HZNP*; *Warner-Lambert* authorities cited above.

Rubicon's non-infringement defense is no shorter or more shrouded than Metacel's infringement contention. The argument was enough for the Court to absorb and agree that infringement would not be inevitable because the Patent's Fridge Limitation required refrigeration, while Rubicon's Generic ANDA label did not.

Metacel next argues that the timing of expert disclosures prejudiced its ability to oppose Rubicon's summary judgment motion because Metacel's opening expert report "could only respond to the cursory identification of the theory in Rubicon's opening brief." Mot. at 7-8. This argument is unpersuasive for the reasons above.

Specifically, Metacel was adequately placed on notice well before Rubicon's latest summary judgment motion of Rubicon's straightforward argument that it did not directly infringe the Fridge Limitation because its [redacted]–first in Rubicon's non-infringement contentions when it argued "no direct infringement," and again when Rubicon sought (albeit unsuccessfully) leave to file its summary judgment motion on July 27, 2022. Any delay in addressing this argument cannot be attributed to Rubicon. But even if it could be, there is no prejudice to Metacel because, for the reasons discussed below, any new information contained in its latest expert report remains insufficient to identify a genuine issue of material fact

B. There is no other basis to reconsider the Opinion

Metacel next argues that the Court overlooked aspects of Rubicon's response to the FDA's query to Rubicon about how it would store its Generic, which would preserve an issue of fact about Rubicon's intent. Specifically, Metacel argues that "Rubicon's true intent regarding storage becomes impossible to ascertain based on the product label alone when Rubicon is willing to tell the FDA that the [redacted] just like the [Reference Listed Drug ("RLD")],[4] but tell this Court the opposite." Mot. at 11. And this alleged conflict, Metacel argues, "cannot demonstrate that Rubicon has no intent to infringe when considering all of the facts and expert reports." Mot. at 12.

Again, this ignores the plain text of the ANDA label, [redacted] But more importantly, Metacel plainly misrepresents the breadth of Rubicon's FDA submission. In fact, Rubicon's submission noted the differences between the RLD's storage statement and its ANDA; the submission informs the FDA that

[4] Ozobax.

[redacted]

See D.E. 104-2 at 77.

Likewise, the supplemental Declaration of Metacel's expert Dr. Savello is also unpersuasive.[5] Distilled, Dr. Savello's theory is that the Generic label's ambiguity would inevitably cause a healthcare provider to consult the RLD's storage instruction, and thus refrigerate the Generic (and infringe the Patent). *See generally* D.E. 147-4 ("Savello Decl."). Phrased differently, pharmacists including Dr. Savello, "[l]acking clear guidance from Rubicon's Product label, … would defer to the [RLD's] storage instructions, and store [the Generic] consistent with the RLD's storage instructions, or simply default to refrigerated conditions [redacted] due to the benefits of refrigeration, such as improved stability of the formulation and/or improved palatability of the formulation." *Id.* at 4, ¶ 10 (cleaned up). But the ANDA label does not "lack clear guidance"—as the Opinion noted, the label unambiguously instructs providers to [redacted]

[5] Metacel recognizes that much of Dr. Savello's supplemental Declaration was not previously presented. Mot. at 9 n.1. These paragraphs cite various sources to argue that that downstream healthcare providers would refer to a brand name drug's RLD statement for refrigeration instructions no matter what a generic's label said. Whatever the merit of this argument, it is clear that the arguments were not previously presented, and thus will not be considered here.

Thus, as the Court previously found, there is no genuine issue of material fact.

Next, Metacel argues that this Court misread and overlooked precedent explaining that the determination of whether an ANDA would induce infringement is a fact question that considers more than the product label. Mot. at 12. The Court disagrees.

As previously held, the label is what matters, because that is what the downstream users—healthcare practitioners, pharmacists, or patients—will rely upon. *See HZNP Meds.*, 940 F.3d at 701-02 (reviewing ANDA label in relation to the asserted claims of the methods-of-use patents to evaluate infringement). And "[m]erely describing the infringing use, *or knowing of the possibility* of infringement, will not suffice; specific intent and action to induce infringement must be shown." *Takeda Pharms.*, 785 F.3d at 631 (emphasis added). But where the label itself describes an infringing use "as an option," but still did not "encourage infringement" or require a claimed step, there is no basis to find infringement. *HZNP Meds.*, 940 F.3d at 702 (no infringement where the label "merely permits applying a second topical agent after the patient waits for the diclofenac sodium to dry"); *see also Grunenthal GmbH v. Alkem Labs Ltd.*, 919 F.3d 1333, 1339-40 (Fed. Cir. 2019) (affirming no inducement where label terminology included but did "not specifically encourage" infringing application); *cf. BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 398 (D.N.J. 2018) ("The only way to follow these labels is to administer abiraterone, together with prednisone, in specified doses, to a mCRPC patient.").

Metacel relies on *Glaxosmithkline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, (Fed. Cir. 2021) ("*GSK*"), and more specifically the Federal Circuit having distinguished *HZNP*. In *GSK*,

"substantial evidence" was before the jury that "Teva's partial label contained information encouraging each claimed step and the preamble."

But before the *GSK* evidence was before the jury, it had to survive summary judgment. *See GlaxoSmithKline LLC v. Glenmark Pharms., Inc.*, 2017 U.S. Dist. LEXIS 82534, at *41, *adopted, obj. overruled by* 2017 U.S. Dist. LEXIS 88839 (D. Del. June 9, 2017). And unlike the evidence presented in Metacel's summary judgment opposition (or here), the *GSK* summary judgment motion demonstrated that the label *itself*, together with marketing materials, constituted "*circumstantial evidence* that could lead a factfinder to believe that the alleged acts of encouragement led to some amount of 'successful communication' between the alleged inducer … and the third-party direct infringer." *Id.* at *40-43 (denying defendants' summary judgment motion where plaintiffs presented defendants' labels and defendants' "touting of the AB rating of their generic … for the entire infringement period from 2008-2015 in their product catalogs, websites, price sheets, Monthly Prescribing Reference ("MPR") and Generic Product Reference Guide"). Unlike *GSK*, *HZNP*'s summary judgment motion, like Rubicon's underlying summary judgment motion, was granted "given the lack of evidence that the *label* encouraged, recommended, or promoted users to perform" the claimed steps (in *HZNP*, two of three claimed steps). *GSK*, 7 F.4th at 1330 (emphasis added) (explaining and reaffirming *HZNP*'s reasoning).

Finally, Metacel argues that granting its motion to reconsider will serve judicial economy because the issues it urges the Court to reconsider or consider for the first time, *e.g.*, supplemental expert reports, will need to be addressed in Rubicon's counterclaim for sham litigation. Mot. at 15. Doing so would, Metacel argues, "avoid estoppel issues and unnecessary motion practice concerning evidence related to the first litigation." *Id.* Metacel cites no support for this argument, and the Court cannot locate any.

III. CONCLUSION AND ORDER

For the reasons above, it is **ORDERED** that Metacel's motion for reconsideration (D.E. 146) shall be **DENIED**.

August 31, 2023

Evelyn Padin, U.S.D.J.